

Title 10
DEPARTMENT OF HEALTH AND MENTAL
HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.33 Prescription Drug Repository Program

Authority: Health-General Article, §§15-601—15-609, Annotated Code of Maryland

Notice of Proposed Action

[15-400-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations **.01—.06**, adopt new Regulations **.01-1** and **.06-1**, repeal existing Regulation **.07** and adopt new Regulation **.07**, and repeal existing Regulations **.08—.12** under **COMAR 10.34.33 Prescription Drug Repository Program**. This action was considered by the Board of Pharmacy at a public meeting held October 21, 2015 notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from September 21, 2015 — October 21, 2015, pursuant to the General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to allow for the disposal of prescription drugs and medical supplies, including controlled dangerous substance as allowed by the Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended).

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact. The Prescription Drug Repository Program is a voluntary program. Those pharmacies that volunteer to participate may incur minimal costs depending on whether or not those pharmacies (1) collect prescription drugs and medical supplies for disposal; and/or (2) collect donated prescription drugs and medical supplies for redispensing to the needy. The Board would not incur additional expenses now that participants in the program may collect controlled dangerous substances for disposal. Pharmacies that participate would be inspected annually as a matter of course.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Indeterminable

- E. On other industries or trade groups: NONE
- F. Direct and indirect effects on public: (+) Indeterminable

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D. Pharmacies that volunteer to participate may incur minimal costs depending on whether or not those pharmacies 1) collect prescription drugs and medical supplies for disposal; and/or 2) collect donated prescription drugs and medical supplies for redispensing to the needy.

F. The public would benefit by having a means to dispose of controlled dangerous substance prescriptions that may be expired or unwanted in their homes. This will reduce accidental overdoses, ingestion by household pets, or theft by family members.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through January 27, 2016. A public hearing has not been scheduled.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(1-1) *“Donation program” means pharmacies that voluntarily participate as a drop-off site or repository, or both, to accept donated drugs or medical supplies for purposes of re-dispensing those donated drugs or medical supplies to needy individuals.*

(1-2) *“Disposal program” means pharmacies that voluntarily participate as repositories to collect returned drugs and medical supplies for purposes of safe disposal.*

(2) *“Drop-off site” means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies as part of the donation program and forwarding the drugs or medical supplies to a repository.*

(3)—(7) (text unchanged)

(8) *“Repository” means a pharmacy that applies to and is designated by the Board for the purpose of:*

(a) *Accepting, inspecting, and dispensing donated prescription drugs or medical supplies received from a drop-off site as part of the donation program; and*

[(b) Inspecting donated prescription drugs or medical supplies; and

(c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.]

(b) Collecting prescription drugs or medical supplies for disposal as part of the disposal program.

.01-1 Incorporation by Reference.

In this chapter, the Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended), has been incorporated by reference.

.02 Donation Program—Eligible Drugs.

A. — B. (text unchanged)

.03 Donation Program—Ineligible Drugs.

A. — B. (text unchanged)

.04 Donation Program—Donor Form.

A. — B. (text unchanged)

.05 Donation Program—Drop-Off Sites Requirements.

A. — C. (text unchanged)

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) (text unchanged)

(2) A drop-off site may not:

(a)—(b) (text unchanged)

(c) Charge a fee for accepting a donation; [or]

(d) Accept donated prescription drugs or medical supplies until the drop-off site applicant has been approved by the Board; or

(e) *Accept prescription drugs for disposal.*

.06 Repositories—General Requirements.

A. In order to become a repository, a pharmacy:

(1) (text unchanged)

(1-1) *Shall indicate on the application to the Board if the applicant intends to:*

(a) *Participate in the Donation Program;*

(b) *Participate in the Disposal Program by collecting only non-controlled dangerous substances and medical supplies for safe disposal; or*

(c) *Participate in the Disposal Program by collecting controlled dangerous substances, non-controlled dangerous substances, and medical supplies for safe disposal;*

(2)—(4) (text unchanged)

[B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

C. Record Requirements. A repository shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.]

.06-1 Repositories Participating in the Donation Program.

A. Designated Pharmacist. A repository in the donation program shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

B. Record Requirements. A repository in the Donation Program shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies for a minimum of 5 years;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies for a minimum of 5 years; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

C. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository in the Donation Program shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.

D. *Limitations.* A repository in the Donation Program is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.

E. *Procedure for Dispensing Donated Prescription Drugs or Medical Supplies.* A repository in the Donation Program shall dispense donated prescription drugs or medical supplies in compliance with applicable federal and State laws and regulations for dispensing prescription drugs or medical supplies.

F. *Procedure for Shipping Donated Prescription Drugs or Medical Supplies.* A repository in the Donation Program shall comply with COMAR 10.34.25 when shipping donated prescription drugs or medical supplies to recipients of this Program.

G. *Procedures for Disposing of Donated Prescription Drugs or Medical Supplies.*

(1) A repository in the Donation Program shall dispose of donated prescription drugs or medical supplies that do not meet the eligibility requirements of Regulation .02 of this chapter.

(2) A repository in the Donation Program shall dispose of donated prescription drugs or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.

(3) A repository shall maintain records of disposal of donated prescription drugs or medical supplies.

H. *Determination of Patient Eligibility for the Donation Program.*

(1) A recipient of the Donation Program shall be a resident of the State.

(2) A health care practitioner with prescribing authority shall:

(a) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Donation Program; and

(b) Indicate on the patient's prescription eligibility for the Donation Program.

I. *Recipient Form.* Recipients of a donated prescription drug or medical supply under the Donation Program shall sign a Board approved form before receiving the prescription drug or medical supply to confirm that the recipient understands that:

(1) The recipient is receiving prescription drugs or medical supplies that have been donated as part of the Donation Program; and

(2) Entities involved in the Donation Program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

.07 Disposal Program—Requirements.

A. Pharmacies that collect returned prescription drugs or medical supplies for proper disposal shall be approved by the Board as repositories.

B. Repositories that collect only non-controlled dangerous substances for proper disposal shall:

(1) Dispose of prescription drugs or medical supplies collected for disposal in compliance with applicable State and federal laws and regulations;

(2) Have policies and procedures regarding the safe and secure handling and disposal of prescription drugs and medical supplies, to include specific guidelines for prescription drugs requiring special disposal or care;

(3) Dispose of collected prescription drugs and medical supplies through a third party processor or a reverse distributor, as appropriate; and

(4) Maintain a separate secure container behind the prescription counter that is clearly marked for the Disposal Program.

C. A pharmacist may not delegate to a pharmacy technician the collection of prescription drugs or medical supplies under §B of this regulation.

D. Repositories that collect controlled dangerous substances for disposal:

(1) Shall comply with the requirements of the Secure and Responsible Drug Disposal Act of 2010;

(2) May collect non-controlled dangerous substances and medical supplies in the same manner; and

(3) May commingle the collection of controlled and non-controlled dangerous substances and medical supplies in accordance with the Secure and Responsible Drug Disposal Act of 2010.

VAN T. MITCHELL
Secretary of Health and Mental Hygiene